UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ENCORE DERMATOLOGY INC., **Plaintiff,** **v.** **GLENMARK PHARMACEUTICALS LIMITED,** **Defendant.**	Civ. No. 20-02509 (KM) (ESK) **OPINION**

KEVIN MCNULTY, U.S.D.J.:

Encore Dermatology has a patent for a topical pharmaceutical composition with the compound clobetasol. The patent also provides that the composition is "propylene glycol-free." Glenmark Pharmaceuticals filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA"), seeking approval for a clobetasol cream that contains propylene glycol. Encore then sued Glenmark, claiming that Glenmark's generic drug would infringe Encore's patent. Glenmark moves to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), arguing that its proposed generic would not infringe Encore's patent because the drug contains propylene glycol. (DE 26.)[1] For the following reasons, the motion is **DENIED**.

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[1] Certain citations to the record are abbreviated as follows:

DE = docket entry

Compl. = Complaint (DE 1)

Glenmark Brf. = Glenmark's Memorandum of Law in Support of its Motion to Dismiss (DE 28)

Encore Opp. = Encore's Opposition to Glenmark's Motion to Dismiss (DE 38)

Glenmark Reply = Glenmark's Reply to Encore's Opposition (DE 42)

I. BACKGROUND

A. Statutory Background

An overview of the framework for drug approvals and related patent disputes is helpful.

"A company wishing to offer a new drug for sale must seek approval from the [FDA] by filing a New Drug Application ('NDA')." *In re Suboxone (Buprenorphine Hydrochlorine & Naloxone) Antitrust Litig.*, 967 F.3d 264, 267 (3d Cir. 2020) (citation omitted). Thereafter, "a generic drug maker may submit an [ANDA] that may rely on a name-brand drug company's original NDA approval for a particular drug in order to gain quicker, less costly FDA approval." *Id.* (quotation marks and citation omitted).

Approved drugs and any patents they rely on are listed in the FDA's "Orange Book." *BTG Int'l Ltd. v. Amneal Pharms. LLC*, 352 F. Supp. 3d 352, 373 (D.N.J. 2018), *appeal dismissed as moot*, 923 F.3d 1063 (Fed. Cir. 2019). An ANDA filer must consult the Orange Book and, as part of its application, attest to how any patents relate to the proposed drug. *Id.* Relevant here, the applicant may assert that a patent "will not be infringed by the applicant's generic compositions," in what is known as a "Paragraph IV certification." *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1374 (Fed. Cir. 2012).

When an ANDA is filed with a Paragraph IV certification, the patent-holder may immediately bring an infringement lawsuit. *See id.* Congress created this unique litigation process for claims involving generic drugs with 35 U.S.C. § 271(e)(2), part of the "Hatch-Waxman Act."[2] *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997). Section 271(e)(2) "established a specialized new cause of action for patent infringement," *AstraZeneca*, 669 F.3d at 1377, and provides, in relevant part:

> It shall be an act of infringement to submit . . . an [ANDA] . . . for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain

[2] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

> approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2)(A).

This provision defines "an act of infringement" in the generic-drug context to mean the submission of an ANDA. Thus, no actual making, using, or selling of a patented device (the "traditional" definition of infringement) is required for an infringement lawsuit to commence. *Glaxo*, 110 F.3d at 1569; *see also* 35 U.S.C. § 271(a). The courts have thus characterized § 271(e)(2) as creating an "artificial" act of infringement. *Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc.*, 978 F.3d 1374, 1381–82 (Fed. Cir. 2020) (collecting cases).

The ultimate merits question in such a suit, as in any infringement suit, is whether the patent covers "the product that is likely to be sold following ANDA approval"—*i.e.,* whether such an eventual sale would constitute "actual infringement." *Ferring B.V. v. Watson Labs., Inc.-Fla.,* 764 F.3d 1401, 1408 (Fed Cir. 2014). The litigation will ultimately test whether the Paragraph IV certification is "erroneous." *AstraZeneca*, 669 F.3d at 1377. But to start litigation, all that is needed is an ANDA with a Paragraph IV certification.

B. This Case

Encore owns U.S. Patent No. 9,956,231 (the "Patent"), which expires in 2030. (Compl. ¶ 17.) The Patent claims "[a] topical pharmaceutical composition comprising: clobetasol; . . . wherein the composition is . . . propylene glycol-free." (*Id.* ¶ 18.) Encore holds an NDA for "Impoyz" cream that uses the Patent's drug. (*Id.* ¶¶ 22–24.)

Impoyz's active ingredient, clobetasol, is used to treat a variety of skin conditions. However, if clobetasol penetrates the skin or if a patient is systemically exposed to clobetasol, the patient may suffer adverse effects. (*Id.* ¶¶ 53–57.) One highly effective skin penetration agent is propylene glycol. (*Id.*) Accordingly, Impoyz does not contain propylene glycol, and the patented composition is described as "propylene glycol-free." (*Id.* ¶ 49.) Nonetheless, the Patent's specification, which provides a background on and description of the

Patent, is perhaps less absolute. It explains that "compositions of the present application are substantially alcohol-free and/or propylene glycol-free, such that any amounts present do not cause significant skin irritation or impart any undesired attributes to the composition." (*Id.*, Ex. C at 7:13–17.)

Glenmark filed an ANDA seeking approval of a clobetasol cream that is a generic version of Impoyz. (*Id.* ¶ 25.) Glenmark's ANDA included a Paragraph IV certification as to the Patent. (*Id.* ¶ 28.) Glenmark notified Encore of its ANDA and explained that its proposed generic does not infringe the Patent because it contains 10% propylene glycol. (*Id.* ¶¶ 29–30.) Glenmark provided Encore only limited access to certain information from its ANDA, so Encore was not able to understand the composition of the proposed generic and how it could safely contain 10% propylene glycol. (*Id.* ¶¶ 35–41, 72–77.) Claiming a "good faith basis to question" Glenmark's assertions, Encore brought this § 271(e)(2) suit. Glenmark moves to dismiss.

II. STANDARD OF REVIEW

Federal Rule of Civil Procedure 8(a) does not require that a pleading contain detailed factual allegations. Nevertheless, "a [party's] obligation to provide the 'grounds' of his 'entitlement to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *see Phillips v. County of Allegheny*, 515 F.3d 224, 232 (3d Cir. 2008) (Rule 8 "requires a 'showing' rather than a blanket assertion of an entitlement to relief." (citation omitted)). Thus, the factual allegations must be sufficient to raise a claimant's right to relief above a speculative level, so that a claim is "plausible on its face." *Twombly*, 550 U.S. at 570. That facial-plausibility standard is met "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). While "[t]he plausibility standard is not akin to a 'probability requirement' . . . it asks for more than a sheer possibility." *Id.*

Rule 12(b)(6) provides for the dismissal of a complaint if it fails to state a claim upon which relief can be granted. The moving party bears the burden of showing that no claim has been stated. *See Animal Sci. Prods., Inc. v. China Minmetals Corp.*, 654 F.3d 462, 469 n.9 (3d Cir. 2011). For the purposes of a motion to dismiss, the facts alleged in the pleading are accepted as true and all reasonable inferences are drawn in favor of the plaintiff. *N.J. Carpenters & the Trs. Thereof v. Tishman Constr. Corp. of N.J.*, 760 F.3d 297, 302 (3d Cir. 2014).

III. DISCUSSION

The parties' primary dispute boils down to whether a complaint that alleges "artificial infringement" alone states a claim. Both parties have fair arguments and case law on their side. Nonetheless, dismissal is inappropriate for two narrower reasons: (1) dismissal requires claim construction of disputed terms, which is improper at this stage, and (2) Encore's good-faith basis to question the ANDA raises a plausible right to relief.

A. The Need for Claim Construction

Non-infringement, even on the face of the pleadings, would require that the Patent's claims indisputably do not cover Glenmark's generic product. *See Glaxo*, 110 F.3d at 1565. The first step in the infringement inquiry, thus, is to construe the claims in the patent ("claim construction"). *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 325 (2015). Claim construction usually is not appropriate on a motion to dismiss, mostly because a fuller record is needed. *Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337, 1349 (Fed. Cir. 2018); *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1343 n.13 (Fed. Cir. 2012); *see also, e.g.*, *Par Pharm., Inc. v. Hospira, Inc.*, No. 17-944-JFB-SRF, 2018 WL 3343238, at *3 (D. Del. May 11, 2018).

Here, the relevant claim provides that the composition is "propylene glycol-free" (Compl. ¶ 18), but it is not indisputably clear whether "propylene glycol-free" means "completely free of propylene glycol" or "free of an amount of propylene-glycol that would be unsafe." That latter construction, says Encore, is suggested by the specification of the Patent, which is the "single best guide"

to construing claim terms and is "[u]sually . . . dispositive." *Bradium Techs. LLC v. Iancu*, 923 F.3d 1032, 1149 (Fed. Cir. 2019) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc)). The specification here provides that the composition is "propylene glycol-free, such that any amounts present do not cause significant skin irritation or impart any undesired attributes to the composition." (Compl., Ex. C at 7:13–17.) Thus, the specification *could* indicate that compositions with some amount of propylene glycol fall within the scope of the claim, so long as the amount of propylene glycol does not have any negative effects. That is far from a necessary interpretation, but it is a possible one.

If the Patent claim is construed to mean that a patented composition could contain some amount of propylene glycol, then it is not indisputably clear on the pleadings that Glenmark has not infringed the Patent. That being so, I could not dismiss the Complaint. *See Eagle Pharms. Inc. v. Hospira, Inc.*, 424 F. Supp. 3d 355, 358–59 (D. Del. 2019) (declining to dismiss complaint because there was a reasonable dispute over whether "non-aqueous" meant the complete absence of water); *Belcher Pharms., LLC v. Int'l Medication Sys., Ltd.*, 379 F. Supp. 3d 326, 333 n.5 (D. Del. 2019) (distinguishing a case that dismissed an ANDA infringement claim on the pleadings because that case was "based on application of a claim construction the Court viewed as not reasonably disputable"). Once the patent has been construed, the second step in the infringement inquiry involves comparing the properly construed claims to the allegedly infringing product. This second step presents a question of fact. *Glaxo*, 110 F.3d at 1165. Accepting the claim construction above, the second step would require deciding whether the amount of propylene glycol in the proposed generic does or does not "cause significant skin irritation or impart any undesired attributes to the composition." (Compl., Ex. C at 7:13–17.) That question, of course, cannot be resolved on the pleadings.

At bottom then, the propriety of dismissal hinges on whether the Patent claim indisputably means that the patented composition is literally free of

propylene glycol. Only then can Glenmark argue that the infringement inquiry can be resolved based on the bare facts in the pleadings.

Yet the specification creates a genuine dispute over claim construction. To be sure, the construction outlined above may not be the best construction or the one that will prevail, because "the specification must always yield to the claim language when identifying the true focus of a claim," *Ericsson Inc. v. TCL Commc'n Tech. Holdings Ltd.*, 955 F.3d 1317, 1325 (Fed. Cir. 2020) (quotation marks, alteration, and citation omitted), and "it is improper to read limitations from the [specification] into a claim," *Bradium Techs.*, 923 F.3d at 1149 (citation omitted). Nonetheless, I "afford the claims their broadest possible construction at this stage of the proceedings" and construe the Complaint in Encore's favor. *Bill of Lading*, 681 F.3d at 1342. Given that leeway, the claim could be read to encompass compositions, like Glenmark's, with an amount of propylene glycol. As a result, there is at least a non-frivolous dispute raised by Encore as to claim construction (Encore Opp. at 22), so resolution of the infringement question on the pleadings would be premature. In other words, I cannot say that as a matter of law Glenmark's product is non-infringing.[3]

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[3] In response, Glenmark first argues that Encore is estopped from arguing that "propylene glycol-free" means "substantially propylene glycol-free" due to Encore's prosecution history and prior amendments to the Patent. (Glenmark Brf. at 13–14.) But such prosecution history is outside the scope of my consideration on a motion to dismiss. *E.g.*, *Deston Therapeutics LLC v. Trigen Labs. Inc.*, 723 F. Supp. 2d 665, 670–71 (D. Del. 2010). For that reason, I deny Glenmark's motion to take notice of supplemental authority (DE 49). Even if I could consider such evidence or materials, there is no basis to conclude that the parties have presented all materials relevant to claim construction. Accordingly, consideration of certain materials and claim construction in general is not appropriate at this juncture. *Deston*, 723 F. Supp. 2d at 671.

Glenmark also argues that even if Encore's preferred claim construction is adopted, the proposed generic would not infringe because it is implausible that a composition with 10% propylene glycol would be covered by that construction. (Glenmark Reply at 11–13.) But applying the properly construed claims to the proposed generic is a question of fact, and there are no facts alleged in the Complaint from which I could firmly make the infringement determination. *E.g.*, *Regents of Univ. of Mich. v. Leica Mircosys., Inc.*, No. 19-CV-07470-LHK, 2020 WL 2084891, at *7 (N.D.

B. Encore's Allegations of a Good Faith Basis to Question the Composition of Glenmark's Proposed Generic

Encore's allegations that it has a good-faith basis to question assertions in Glenmark's ANDA that the proposed generic will contain propylene glycol also suffice to state a claim. *Twombly*/*Iqbal* only requires the Complaint allege "'enough fact[s] to raise a reasonable expectation that discovery will reveal evidence' to support" Encore's allegation that Glenmark's generic will be infringing. *Nalco*, 883 F.3d at 1350 (quoting *Twombly*, 550 U.S. at 556). Encore's alleges that there are good scientific reasons to question how a clobetasol cream could contain the amount of propylene glycol proposed for Glenmark's generic version. That is enough to raise a reasonable expectation that discovery will reveal that the proposed generic is infringing.

I take Glenmark's point that the focus should be on the composition stated in the ANDA, and that Encore's skepticism cannot change the fact that what the ANDA seeks approval for is a generic that would contain propylene glycol. The Federal Circuit has explained that "[b]ecause drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug, an ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry." *Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002). Accordingly, a court cannot entertain "'speculative' claims of infringement," as the analysis is "limited" to "whether what the generic drug maker is requesting authorization for in the ANDA would be an act of infringement if performed." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003).

Nonetheless, Encore is not required to prove its case at this stage. *Nalco*, 883 F.3d at 1350. The purpose of § 271(e)(2) litigation is, in effect, to determine

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Cal. Apr. 30, 2020) ("*[E]ven if* the Court adopted a construction favorable to [defendant], the Court would still need to assess infringement, which itself is a question of fact." (quotation marks and citation omitted)).

whether the Paragraph IV certification is "erroneous." *AstraZeneca*, 669 F.3d at 1377. In some § 271(e)(2) cases, discovery has revealed that a proposed generic in fact contains a compound, and that finding determines or influences the issue of whether there is infringement. *Novartis Pharms. Corp. v. PAR Pharm., Inc.*, 48 F. Supp. 3d 733, 739–40 (D. Del. 2014), *aff'd sub nom. Novartis Pharms. Corp. v. Watson Labs, Inc.*, 611 F. App'x 988 (Fed. Cir. 2015).

I am further swayed by Encore's allegation that, at this point, it has only been furnished limited information, so it has a limited understanding of the composition of the proposed generic. So it is at least plausible, given Encore's limited understanding of the composition, the known interaction of propylene glycol and clobetasol, and the role of discovery in explicating a composition, that there is more to Glenmark's proposed generic and that "something more" renders the proposed generic infringing.

This aspect of Encore's claim may frankly be little more than a makeweight for the more substantial, claim construction issue. Encore itself seems to leave open the possibility of modifying its contentions based on further information, which it does not now possess. But the issue of the composition of Glenmark's generic will have to be explored in any event. I will therefore permit this aspect of the claim to go forward.

IV. CONCLUSION

For the reasons set forth above, the motion to dismiss is denied. A separate order will issue.

Dated: December 22, 2020

/s/ Kevin McNulty

Hon. Kevin McNulty
United States District Judge